IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT

UCB, INC., UCB PHARMA GMBH, and LTS LOHMANN THERAPIE-SYSTEME AG.,

Plaintiffs/Counterclaim Defendants.

Case No. 2:22-cv-00216 CR

V.

MYLAN TECHNOLOGIES INC.,

Defendant/Counterclaim Plaintiff.

REPLY REGARDING REQUEST FOR STATUS CONFERENCE

Mylan's straightforward Request sought a status conference to discuss how to proceed efficiently with the remaining issues in the case considering the Federal Circuit's decision, including early dispositive motion practice on a threshold issue. Plaintiffs have brought claims they are not entitled to pursue. Half are controlled by the Federal Circuit's recent decision, and the other half were settled by a Covenant Not to Sue ("CNS") several years ago, making their viability a question of contract interpretation. Plaintiffs' insistence on proceeding with burdensome discovery while delaying resolution of these dispositive threshold issues significantly prejudices Mylan and needlessly prolongs a case that should not have been brought again.

I. '598 and '174 Patents: The Federal Circuit's Decision

While it is true that Plaintiffs may still file a request for rehearing of the appeal under Fed. Cir. R. 40, that does not justify delaying a teleconference. Rehearing requests are rarely granted, making it highly likely the decision will stand; this necessarily results in the scope of this case being narrowed. And in the meantime, Plaintiffs continue pursuing discovery on these claims despite there now being an adverse judgment on the merits. Plaintiffs understandably wish to

postpone discussing the impact of the decision on this case, but they have not identified (and cannot identify) good grounds to do so—particularly given that the parties already discussed with the Court the implications of the Federal Circuit appeal in the previous action. *See* Civ. No. 2:19-cv-128, Dkt. No. 140 (Transcript of June 2, 2021 Conference) at 3:18-20; *id.* Dkt. No. 141 (Transcript of June 7, 2021 Conference) at 4:5-11; *see also id.* Dkt. No. 128 (Joint Stipulation and [Proposed] Order to Stay Litigation Pending Appeal (May 14, 2021)) at 1-2.

II. '979 and '980 Patents: Covenant Not to Sue

As to the claims covered by Plaintiffs' CNS, Plaintiffs misrepresent Mylan's position. Mylan does not seek to alter or amend the Scheduling Order, because it already provides that summary judgment motions may be filed "on, *or before*, October 31, 2023." Dkt. No. 48 at 7 (emphasis added). Rather, Mylan seeks to efficiently dispose of, or at least further streamline, this action with an early dispositive motion. It seeks the Court's guidance on how best to proceed in that regard. And that is because it is profoundly prejudicial to Mylan to be forced to defend claims that are barred by a binding CNS any longer than necessary. Plaintiffs' decision to sue a second time on these patents has automatically stayed regulatory action, delaying approval of Mylan's ANDA product and disrupting its settled expectations. *See* 21 USC § 355(j)(5)(B)(iii); 21 CFR § 314.96.

The CNS prohibits Plaintiffs from suing Mylan on the '979 and '980 patents unless Mylan makes changes in its product that "alter the infringement analysis." Plaintiffs invoke the allegations of their Complaint to suggest that they need extensive and technical discovery to determine whether the CNS applies. Not so. The term "alter the infringement analysis" must mean something. Here, there is no basis to maintain that the infringement analysis ever changed. No additional discovery is needed to resolve that threshold question. To the extent Plaintiffs disagree, that is

what an opposition to summary judgment is for. At bottom, the CNS presents an issue of *contract interpretation* whose resolution will determine whether the CNS precludes Plaintiffs' claims.

Plaintiffs' repeated references to a "reformulated ANDA product" miss the mark because they do not address the right question. The issue is whether there was any alteration of the infringement analysis. There was not. Mylan's ANDA is the same as its original ANDA in all material aspects relevant to the infringement analysis for the '979 and '980 patents. The claims are ripe for summary judgment, and Mylan respectfully reiterates its request that the Court schedule a conference so that these issues can be discussed in greater detail.

Dated: May 4, 2023 Respectfully submitted,

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